REMARKS

Reconsideration and withdrawal of the rejections are respectfully requested. Claims 2, 5 and 6 having been, the pending claims in the above-identified application are claims 1, 3-4 and 7-13. No new matter has been added.

Double Patenting Rejection

Claims 1, 3 and 4 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,965. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

Rejection Under 35 U.S.C. §101

Claims 1-13 (claims 1, 3-4 and 7-13 as amended) were rejected under 35 U.S.C. §101 as allegedly not being supported by either a specific and substantial credible utility or a well established one. Specifically, the Examiner stated on page 3 of the Office Action that "[t]he asserted utility in this case essentially is a method of treating an unspecified, undisclosed disease or condition, which does not define a 'real world' context of use." This rejection is respectfully traversed.

Applicants respectfully submit that the rejection is contrary to both the law and the United States Patent Office's own examination guidelines. The application of these standards to biotechnology inventions is discussed in the January 5, 2001 Federal Register Notice of the United States Patent Office's Utility Examination Guidelines. Section II.B.1(c)(1) and (2) of the January 5, 2001 "Utility Examination Guidelines" states "[a]n invention has a well-established utility if a person of ordinary skill would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties...), and the utility is specific, substantial, and credible." 66 FR 4, p. 1098. Moreover, "[a] patent examiner must accept a utility asserted by an applicant unless the Examiner has sound scientific reasoning to rebut the assertion." 66 FR 4, p. 1096. To establish a *prima facie* showing of lack of utility, "the Office must ... provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima*

facie showing ... the PTO must do more than merely question operability - it must set forth factual reasons which would lead one of skill in the art to question the objective truth of the statement of operability." M.P.E.P. §2107.02(IV).

Applicants do not understand this rejection. Applicants maintain, however, that after reading the specification one of skill in the art would immediately appreciate the usefulness of the claimed invention. Applicants would like to draw the Examiner's attention to page 67, lines 1-21, which states, in part:

> The zacrp13 gene is located at the 22q12.3 region of chromosome 22. Several genes of known function map to this region that are linked to human disease. For example, monosomy of chromosome 22, and less frequently the loss or translocation of distal 22q, is the most common chromosomal abnormality observed in meningioma tumors .... Moreover, the most frequent cytogenetic abnormality in aggressive malignant mesotheliomas is loss of chromosome 22, as well as loss of 22q11.21-q13.1 in acoustic neuromas .... Thus, since the zacrp13 gene maps to chromosome 22q12.3, the zacrp13 polynucleotide probes of the present invention can be used to detect and diagnose the presence of chromosome 22 monosomy and other chromosome 22q12.3 loss, and particularly chromosome 22 monosomy and loss associated with meningiomas, and other human tumors. Moreover, translocation between chromosome 22q12 and chromosome 11q24 (t(11;22)(q24;q12)) is associated with Ewing sarcoma, and other related tumors. Thus, the zacrp13 polynucleotide probes of the present invention can be used to detect and diagnose chromosome 22q12 translocation associated with human disease, such as Ewing sarcoma.

"A diagnostic could assist physicians in determining the type of disease and appropriate therapy, or assistance in genetic counseling" (page 68, lines 9-10 of the specification). Thus, Applicants submit that the ability to detect and diagnosis specific human diseases is a beneficial real world use.

The Examiner has provided no evidence or scientific basis to refute the assertions of utility for the nucleic acid molecules of the present invention. The invention indeed has a specific asserted and a well-established utility for the claimed nucleic acid

molecules that are supported by the specification (see above). Thus, Applicants submit that the Examiner has not established a *prima facie* showing of lack of utility, because it has not provided sound scientific reasoning to rebut the assertion of utility in the application and the evidence presented by Applicants therein. In view of the Examiner's apparent failure to note and evaluate this evidence, Applicants submit that a *prima facie* showing of no specific and substantial credible utility has not been made.

For the above reasons, Applicants respectfully submit that the invention recited in claims 1, 3-4 and 7-13 is useful. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-13 (claims 1, 3-4 and 7-13 as amended) under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner stated on page 5 of the Office Action that "since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention." This rejection is respectfully traversed.

In light of the above remarks with respect to utility, reconsideration and withdrawal of the rejection of claims 1, 3-4 and 7-13 under 35 U.S.C. §112, first paragraph, are respectfully requested.

The Examiner also rejected claims 1-6 (claims 1 and 3-4 as amended) under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

"A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to

rebut the presumption. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of the evidence why a person of skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." M.P.E.P. §2163. In determining whether an applicant has satisfied the written description requirement, the "fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." M.P.E.P. §2163.02. "Such possession is effective if one of ordinary skill in the art could have combined the publication's description of the invention with his knowledge to make the claimed invention." Flehmig v. Giesa, 13 USPQ2d 1052, 1055 (B.P.A.I. 1989). The applicant does not have to describe the invention exactly, but it must be clear to one or ordinary skill in the art that the applicant "invented what is claimed." Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

The rejected nucleic acid molecule claims of the present invention (claims 1 and 3-4) are directed towards nucleic acid molecules that encode a polypeptide which includes at least amino acid residues 18-459 of SEQ ID NO:2. Applicants submit that the nucleic acid molecules of claims 1 and 3-4 possess distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention, as of the filing date of the application. Moreover, Applicant submits that the Examiner has failed to establish a *prima facie* case of unpatentability under 35 U.S.C. §112, first paragraph.

Accordingly, reconsideration and withdrawal of the rejection of claims 1 and 3-4 under 35 U.S.C. §112, first paragraph, are respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

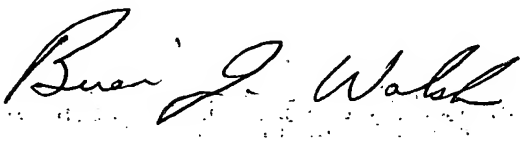
The Examiner rejected claims 2, 5 and 6 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

Applicants have canceled claims 2, 5 and 6 thereby rendering the rejection moot. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Conclusion

In light of the above amendments and remarks, reconsideration and withdrawal of the rejections are respectfully requested. It is, thus, respectfully requested that claims 1, 3-4 and 7-13 are in condition for allowance and notification to that effect is respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6540.

Respectfully Submitted,



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Enclosures:
Petition and Fee for Extension of Time (in duplicate)
Amendment Fee Transmittal (in duplicate)
Postcard